

### **REMARKS**

Claims 52-63 and 65-68 are pending after the present amendments. Applicants reserve the right to prosecute the canceled claims in the future. Applicants respectfully request reconsideration in view of the following remarks.

#### **Claim Rejections under 35 U.S.C. § 112**

The Office rejected claims 1, 3-8, 15-16, 19-20, 36-37 and 52-63 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Office indicated that the phrase “consisting essentially of” is confusing. Furthermore, the Office alleged that there is insufficient antecedent basis for the limitation “complex carbon and/or nitrogen source.”

To expedite prosecution, Applicants have deleted the objected phrase. As amended, the claims recite “comprising,” which clarifies that the claimed fermentation medium may contain an amount of complex carbon and/or nitrogen sources that is at most about 10 % of the total amount of carbon and/or nitrogen. This amendment is supported in the specification at least at page 5, lines 7-13 and at page 6, lines 6-13. Applicants have also amended the claims to recite “an amount of complex carbon and/or nitrogen source.” The claims as amended are clear and definite, and Applicants therefore respectfully request that this rejection be withdrawn.

#### **Claim Rejections under 35 U.S.C. § 103**

The Office rejected claims 1, 3-8, 15-16, 19-20, 36-37 and 52-63 under 35 U.S.C. § 103(a), as allegedly being unpatentable under Sheehan (U.S. patent 4,164,445) in view of Microbiology, fourth edition (Pelezar, Reid, and Chan, pages 853-856). The Office acknowledges that Sheehan *et al.* do not teach the process of the production of beta-lactam comprising the steps of fermenting on a volume scale of at least 10 m<sup>3</sup>. However, the Office alleged that “[i]t would have been obvious . . . to modify Sheehan et al.’s teaching and to include the beneficial teachings of Microbiology because the above two combined reference teachings utilizing the same process steps would produce an improve [sic] process for the production of Beta-Lactam at an industrialized scale.” (Office action, page 4). Applicants must respectfully disagree.

As amended, the claims exclude alcohols as a carbon source. Sheehan, alone or in combination with the Microbiology reference, fails to teach a process comprising fermenting a microbial strain on a volume scale of at least  $10\text{ m}^3$ , in a fermentation medium containing an amount of complex carbon and/or nitrogen source that is at most about 10 % of the total amount of carbon and/or nitrogen. In the absence of ethanol, the carbon sources used in Sheehan are cornsteep liquor (1.8 %), and glucose hydrate (0.20 %). (See Sheehan patent at col. 3:2-15). As indicated in the specification, cornsteep liquor is a complex carbon source. (See, specification at page 1, lines 21-24). Thus, the carbon source in Sheehan, in the absence of ethanol, is primarily composed of corn steep liquor, a complex carbon source.

Even if combined with the Microbiology reference, the combination fails to teach the invention as claimed. As shown in Figure 40-4, the Microbiology reference teaches the manufacture of penicillin using a medium of corn-steep liquor, lactose, salts and other ingredients. However, the Microbiology reference does not teach the percentage composition of the fermentation medium, let alone a fermentation medium having an amount of complex carbon and/or nitrogen source that is at most about 10 % of the total amount of carbon and/or nitrogen sources. If combined with the Sheehan patent, the fermentation medium would comprise 1.8 % of cornsteep liquor and 0.20 % of lactose.

Because Sheehan, alone or in combination with the Microbiology reference, fails to teach all the elements of the invention as claimed, the claims are non-obvious. Furthermore, there is no reasonable expectation of success that a fermentation medium comprising an amount of complex carbon and/or nitrogen source that is at most about 10 % of the total amount of carbon and/or nitrogen sources may be used for large scale  $\beta$ -lactam production. As indicated in the specification, the product yields which would be obtained using chemically defined media on an industrial scale were typically considered to be substantially lower than those obtained using media containing complex raw materials. In addition, high-producing microbial strains which have been developed for industrial processes in complex media were suspected not to retain their good performance in chemically defined media. (See, Specification at 2:34-3:7).

Based on the above, the claims are nonobvious. Thus, Applicants respectfully request that the rejections under 35 U.S.C. § 103 be withdrawn, and the claims be passed to allowance.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 246152012710. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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